IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BOARD OF PATENT APPEALS AND INTERFERENCES

In re:

Title:	Glycoluril Core Molecules for Combinatorial Libraries
Inventors:	Rebek, et al.
Filing Date:	February 9, 1999
Serial Number:	09/246,468
Examiner:	Garcia, M.
Art Unit:	1627
Applicant's Ref.:	TSRI 659.0

#17
Brigg
2-25-02

Appeal Brief

Commissioner of Patents & Trademarks

Washington, D.C. 20231

Sir:

The Applicant appeals the Final Rejection (March 9, 2001) of claims 1-15 as maintained in the Advisory Action dated October 1, 2001.

Real Party in Interest

The real party in interest is The Scripps Research Institute, the Assignee of the subject patent application.

Related Appeals and Interferences

There are no related Appeals or Interferences.

Status of Claims

Claims 1-15 are pending and stand rejected. Claims 16-34 have been cancelled without prejudice or disclaimer in response to a Requirement for Restriction dated April 11, 2000. Applicant appeals the rejection of claims 1-15.

Status of Amendments

A Response to the Office Action of March 9, 2001 was filed on September 11, 2001. No Amendments were made to the claims. The Response presented arguments against the pending claim rejections. The Response was considered but was not deemed sufficient to overcome the rejections.

Summary of Invention

The subject invention is novel core molecules used as supports for constructing a combinatorial library (page 1, lines 7-8; page 4, lines 14-15; page 6, lines 4-6).

Issues

First Issue: Are the claimed core molecules of claims 1-15 useful as required by 35 U.S.C. §101?

Second Issue: Does the specification enable one of skill in the art to use the molecules of claims 1-15 as required by the first paragraph of 35 U.S.C. §112?

Grouping of Claims

Claims 1-15 stand or fall together.

Argument

First Issue: Rejection No. 1 under 35 U.S.C. § 101:

The Examiner has rejected claims 1-15 under 35 U.S.C. §101 as allegedly lacking either a specific asserted utility or a well established utility. The Examiner states at paragraph 9 of the June 20, 2000 Office Action that the only utility disclosed for the claimed molecules is that they can be used as core molecules for constructing a combinatorial library. The Examiner further states that the issue is "whether the fact that the claimed compounds can be used to create combinatorial libraries that can be screened, without more, constitutes an 'immediate benefit to the public'". The Examiner relies on Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA) 1980) for establishing the "benefit to the public" standard.

Based on the above statement of utility standards, the Examiner concludes that the claimed compounds have no immediate exploitable benefit to the public because the members of the combinatorial library are not shown to possess any particular biological activity. Applicants respectfully submit that this rejection is not well taken.

The Examiner confuses the claimed core molecules of the subject invention with the individual members of the combinatorial library made using the core molecules. First, the claims are not directed to the library *per se* or individual members of the library. The invention is directed to the core molecules. Thus, it doesn't matter whether the library members have been shown to have biological activity; in other words, the utility of the library members is **NOT** the issue. Rejection of the claimed core molecules based on the perceived lack of utility of the non-claimed library members is simply inappropriate. Utility is to be based on the claimed invention, not on an unclaimed component of the specification. Second, the core molecules of this invention are not intermediate precursors to the library members. The core molecules serve as a

soluble scaffold upon which a combinatorial library is made. Upon completion of the library construction, individual members are removed from the core molecules. Thus, the series of cases dealing with utility of chemical intermediates is inapposite to the present invention.

The Examiner, at paragraph 12 of the June 20, 2000 Office Action, continues by asserting that the claimed compounds are "objects of research" and not "research tools" and, thus, not accorded the "unquestioned utility" of "research tools". Applicants find this to be a distinction without a difference. First, the assignment of the claimed molecules to the class of "research objects" rather than "research tools" is arbitrary and capricious. Once again, the Examiner is confusing the claimed core molecules with the unclaimed library members. The claimed core molecules are **NOT** the objects of further research: rather, they are explicitly defined chemical structures shown to be useful as providing a backbone upon which libraries can be synthesized. Indeed, a detailed description of how to activate a claimed core molecule such that the core molecule can be used as a soluble scaffold for attaching building blocks to make a combinatorial library can be found in the specification at page 17, line 8 to page 18, line 22.

The claimed invention is a core molecule, not a member of a combinatorial library. At page 4, lines 14 and 15, the specification specifically recites that the present invention provides a core molecule for use in constructing a combinatorial library. At page 6, lines 4, 5, and 6, the specification explicitly states that the present invention provides core molecules for use in combinatorial organic chemistry and for use in preparing and deconvoluting combinatorial libraries. A detailed description of the utility of the present invention can be found in the specification at page 17, line 8 and continuing to page 20, line 13. Applicants respectfully submit that the above statements constitute an assertion of a credible utility.

Second Issue: Rejection No. 2 under 35 U.S.C. § 112, first paragraph:

The Examiner has rejected claims 1-15 under the first paragraph of 35 U.S.C. 112, for an alleged lack of enablement. In particular, the Examiner asserts that, because the claimed invention is allegedly not supported by a specific utility, the specification does not teach one of ordinary skill in the art how to use the invention. Applicants argue against this rejection.

A. Support for the compound of claim 1 can be found in the specification at page 4, lines 15-21 and page 9, lines 8-19. Support for the compound of claim 2 can be found in the specification at page 4, lines 15-21 and page 9, lines 8-19. Support for the compound of claim 3 can be found in the specification at page 4, lines 15-21 and page 9, lines 8-19 and page 10. Support for the compound of claim 4 can be found in the specification at page 4, lines 15-21 and page 9, lines 8-19 and page 10. Support for the compound of claim 5 can be found in the specification page 4, lines 15-21 and page 9, lines 8-19 and page 11. Support for the compounds of claims 6-8 can be found in the specification at page 4, lines 15-21 and FIG. 4. Support for the compounds of claim 9-14 can be found in the specification at page 4, lines 15-21 and FIG 7.

B. The specification at pages 14, 15, and 20-25 and in FIGs 1-4, 6, 10 and 11 shows how to make the claimed compounds. The specification at pages 15-20 discloses how to use the claimed compounds as a soluble scaffold (core molecule) for constructing and deconvoluting a combinatorial library.

C. The specification at pages 14, 15, and 20-25 and in FIGs 1-4, 6, 10 and 11 shows the best mode on how to make the claimed compounds. The specification at pages 15-20 discloses the best mode on how to use the claimed compounds as a

soluble scaffold (core molecule) for constructing and deconvoluting a combinatorial library.

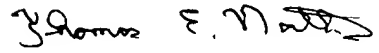
For use in constructing a combinatorial library, the core molecule of the subject invention is activated using a coupling reagent (page 16, line 3), esterification (page 16, lines 12-21) or an amide coupler (page 16, line 22 to page 17, line 7). Following activation, the molecule is then reacted with a building block such as a substituted amine radical (page 17, line 9 to page 18, line 3). Examples of uses of the claimed compound can be found in Examples 6, 7 and 8 (pages 23-25).

In light of the above, the Examiner's assertion that one of ordinary skill in the art could not use the claimed invention is not well taken.

SUMMARY

The invention is a core molecule that serves as a soluble scaffold for preparing a combinatorial library. Explicit recitation of the utility can be found throughout the specification. The specification further discloses detailed teachings of how to make and use the core molecules of claims 1-15. Applicants therefore respectfully request that the rejection of claims 1-15 under 35 U.S.C. sections 101 and 112 (first paragraph) be overturned.

Respectfully submitted,

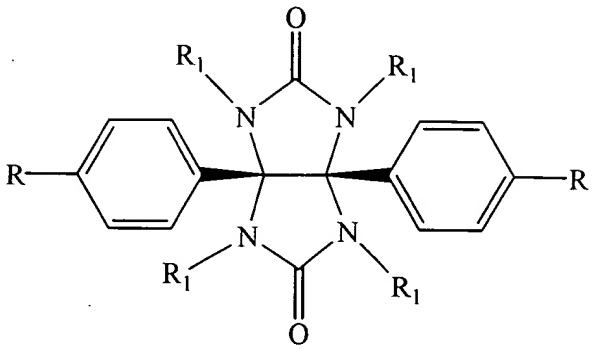


Thomas E. Northrup
Reg. No. 33,268
The Scripps Research Institute
10550 N. Torrey Pines Road, TPC-8
La Jolla, CA 92037
November 7, 2001
(858) 784-2937

P:\NANCY\WP\OA\NOV0088P.APPEALBRIEF

APPENDIX A

1. A compound of the structure I, below



I

where each R is independently hydrogen or $-OR_1$, each R_1 is independently hydrogen or CH_2COOR_2 and each R_2 is independently hydrogen, C_1-C_6 alkyl, C_1-C_6 alkenyl, C_1-C_6 alkynyl, C_6 aryl, or C_6-C_9 aralkyl, with the proviso that at least R_1 be CH_2COOR_2.

2. The compound of claim 1 wherein each R is hydrogen.

3. The compound of claim 1 wherein each R is OR_1.

4. The compound of claim 1 wherein two of the R_1 groups are hydrogen.

5. The compound of claim 1 wherein each R is OR_1 and two of the R_1 groups are hydrogen.

6. The compound of claim 1 wherein R_2 is a C_6 aryl.

7. The compound of claim 6 wherein the C_6 aryl is a halo-substituted C_6 aryl.

8. The compound of claim 7 wherein the halo-substituted C_6 aryl is C_6F_5.

9. The compound of claim 1 wherein R_2 is a C_2 alkyl.

10. The compound of claim 9 wherein the C_2 alkyl is ethyl.

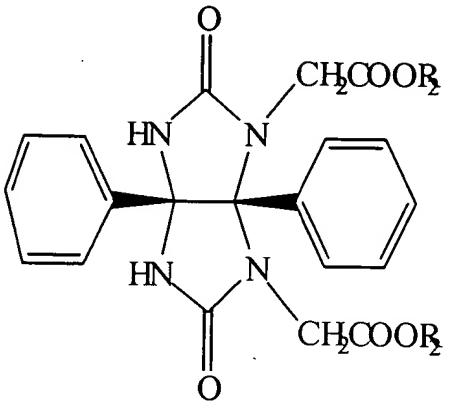
11. The compound of claim 9 wherein the C_2 alkyl is halo-substituted C_2 alkyl.

12. The compound of claim 11 wherein the halo-substituted C_2 alkyl is 2,2,2-trichloroethyl.

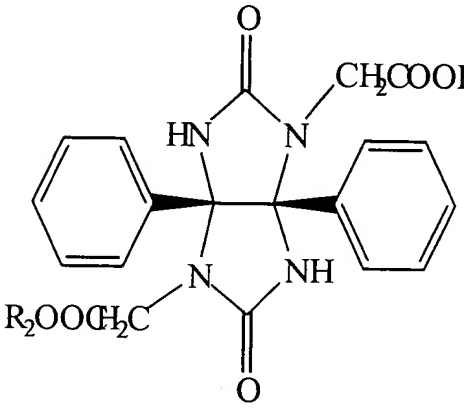
13. The compound of claim 1 wherein R_2 is a C_7 aralkyl.

14. The compound of claim 13 wherein the C_7 aralkyl is benzyl.

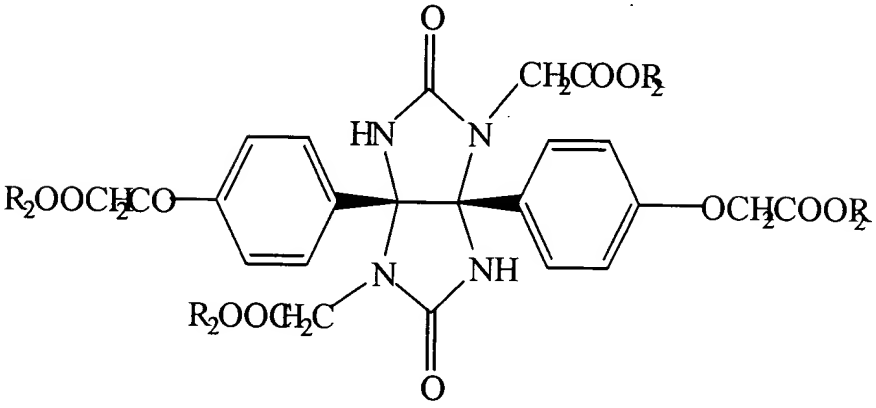
15. The compound of claim 1 having the structure



;



;



; or